

Safety Data Sheet
Ivermectin Cream, 1%
Strength: 1%

Pack Size:
30 gram NDC 72578-120-06
45 gram NDC 72578-120-08
60 gram NDC 72578-120-02

Revision: 00

Emergency Overview

Ivermectin cream, 1% is a white to pale yellow homogeneous cream. Each gram of ivermectin cream contains 10 mg of ivermectin, USP. It is intended for topical use. Ivermectin is a semi-synthetic derivative isolated from the fermentation of *Streptomyces avermitilis* that belongs to the avermectin family of macrocyclic lactones.

Section 1:

Identification

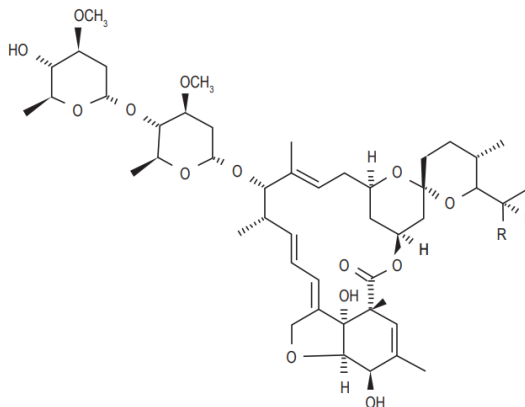
Product Name:

Ivermectin Cream, 1%

Formula:

Ivermectin is a mixture containing not less than 95.0 % and not more than 102.0 % of 5-O-demethyl-22,23-dihydroavermectin A1a plus 5-O-demethyl-25-de(1-methylpropyl)-25-(1-methylethyl)-22,23-dihydroavermectin A1a, generally referred to as 22,23-dihydroavermectin B1a and B1b or H2 B1a and H2 B1b, respectively; and the ratio (calculated by area percentage) of component H2 B1a/(H2 B1a + H2 B1b) is not less than 90.0 %. The respective empirical formulas of H2 B1a and H2 B1b are C₄₈H₇₄O₁₄ and C₄₇H₇₂O₁₄ with molecular weights of 875.10 and 861.07 respectively

Chemical Structure:



Description:

Ivermectin cream, 1% is a white to pale yellow homogeneous cream. Each gram of Ivermectin cream contains 10 mg of ivermectin, USP. It is intended for topical use.

Dosage forms and strengths:

Cream, 1%.
Each gram of ivermectin cream contains 10 mg of ivermectin, USP in a white to pale yellow homogeneous cream. Ivermectin cream is supplied in tubes of 30 g, 45 g and 60 g.

Manufacturer / supplier identification

**Company
Address**

Zydus Lifesciences Ltd. Changodar, Ahmedabad. India
Cadila Healthcare, Ltd. Changodar, Ahmedabad (Topical Formulation facility)
Plot No. 254/255, Sarkhej-Bavla, N. H 8A, Changodar. Tal. – Sanand. Dist. - Ahmedabad -382210. India.

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Contact for information
Emergency Telephone No
US customer service no.

Tel.:+91 2717-616430 Fax: +91 2717-616430
Tel.:+91 2717-616401
1 (877) 993 8779

Recommended use / Therapeutic Category

Ivermectin cream is indicated for the treatment of inflammatory lesions of rosacea

Restriction on Use
/
Contraindications

None

Section 2: Hazard (s) Identification

Dose and Administration

Apply to the affected areas of the face once daily. Use a pea-size amount for each area of the face (forehead, chin, nose, each cheek) that is affected. Spread as a thin layer, avoiding the eyes and lips. Ivermectin cream is not for oral, ophthalmic or intravaginal use.

Adverse effects

Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

During clinical trials, 2,047 subjects with inflammatory lesions of rosacea received ivermectin cream once daily. A total of 1,555 subjects were treated once daily for more than 12 weeks and 519 for approximately one year.

Adverse reactions, reported in $\leq 1\%$ of subjects treated with ivermectin cream for at least 3 months in vehicle-controlled clinical trials, included skin burning sensation and skin irritation

Postmarketing Experience

Because adverse reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Local adverse reactions: contact dermatitis and allergic dermatitis.

Over Dose Effect

In accidental or significant exposure to unknown quantities of veterinary formulations of ivermectin in humans, either by ingestion, inhalation, injection or exposure to body surfaces, the following adverse effects have been reported most frequently: rash, edema, headache, dizziness, asthenia, nausea, vomiting and diarrhea. Other adverse effects that have been reported include: seizure, ataxia, dyspnea, abdominal pain, paresthesia, urticaria and contact dermatitis. In case of accidental ingestion, supportive therapy, if indicated, should include parenteral fluids and electrolytes, respiratory support (oxygen and mechanical

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ventilation if necessary) and pressor agents if clinically significant hypotension is present. Induction of emesis and/or gastric lavage as soon as possible, followed by purgatives and other routine anti-poison measures, may be indicated if needed to prevent absorption of ingested material.

Pregnancy Comments

Risk Summary The available data on the use of ivermectin, including ivermectin cream, in pregnant women are insufficient to establish a drug- associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes.

Section 3: Composition / information on ingredients

Each gram of ivermectin cream contains 10 mg of ivermectin

Section 4: First -aid measures

INGESTION:

Accidental ingestion of product may necessitate medical attention. In case of accidental ingestion dilute with fluids (water or milk) and treat symptomatically. Do not induce vomiting. Never give anything by mouth to an unconscious person. Contact the nearest Poison Control Center or local emergency number. Provide an estimate of the time and amount of the substance swallowed.

EYES:

If the product is in the eyes, do not rub eyes. Flush with copious amount of lukewarm water for at least 15 minutes. Open and close eyelid to ensure thorough irrigation. If irritation persists contact a physician. Remove contacts if applicable.

SKIN:

If redness, dryness or other signs of irritation occur wash the affected area with warm water and soap. If irritation persists contact a physician.

INHALATION:

If respiratory irritation occurs, remove individual to fresh air.

MEDCAL CONDITIONS AGGRAVATED BY EXPOSURE: None known.

Section 5: Fire -fighting measures

FLASH POINT:

>60

AUTO IGNITION TEMPERATURE:

N/A

FLAMABILITY LIMITS: LOWER EXPLOSIVE LIMIT:

N/A

UPPER EXPOLISIVE LIMIT:

N/A

EXPLOSION HAZARD:

This product is non-flammable.

EXTINGUISHING METHODS:

Foam, CO₂, dry chemical powder, water spray, sand/earth as applicable to surrounding fire conditions.

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FIRE-FIGHTING PROCEDURES:

As in any fire, wear MSHA/NIOSH approved self-contained breathing apparatus (pressure-demand) and full protective gear as applicable to surrounding fire conditions.

Section 6: Accidental Release Measures

PROCEDURES FOR SPILL/LEAK CLEAN-UP:

Caution! Floor may become slippery. Absorb spilled material with inert material such as sawdust, sand or earth. Cleaning may require use of steam, solvents or detergents.

DISPOSAL METHOD:

Sweep up and dispose of in accordance with Federal, State and local regulations.

Section 7: Handling and Storage

WORK AND HYGENE PRACTICES:

Use only as directed. Avoid eye contact.

STORAGE AND HANDLING:

Use and store according to labeled directions. Do not store in unmarked or damaged containers or storage devices. Keep containers securely closed when not in use.

SPECIAL PRECAUTIONS:

Spilled material may present a slipping hazard if left unattended. Clean spills promptly.

Section 8: Exposure controls/personal protection

VENTILATION AND ENGINEERING CONTROLS:

None required.

RESPIRATORY PROTECTION:

None required.

EYE PROTECTION:

None required under normal conditions or use. Avoid eye contact, moderate irritation may result. May cause irritation in some sensitive individuals.

HAND PROTECTION:

Not required under normal conditions of use. May cause skin irritation in some sensitive individuals.

BODY PROTECTION:

None required.

Section 9: Physical and chemical properties

VAPOR DENSITY:

N/A

BOILING POINT:

N/A

MELTING POINT:

N/A

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EVAPORATION RATE:	N/A
VAPOR PRESSURE:	N/A
WATER SOLUBILITY:	Miscible
COLOR:	White to Pale Yellow
FRAGRANCE:	Characteristic
APPEARANCE:	Cream
VISCOSITY:	Approx. 60,000 cps

Section 10: Stability and reactivity

STABILITY:	This product is stable.
REACTIVITY:	Stable at room temperature (30°C)
HAZARDOUS DECOMPOSITION PRODUCTS:	If exposed to extremely high temperatures, products of thermal decomposition may include irritating vapors and toxic gases (e.g. oxides of carbon and nitrogen).
HAZARDOUS POLYMERIZATION:	Will not occur.
CONDITIONS TO AVOID:	Open flames, high heat, direct sunlight and freezing.
INCOMPATIBLE SUBSTANCES:	None known.

Section 11: Toxicological information

TOXICITY DATA:	This product has not been tested on animals to obtain toxicological data.
CHRONIC TOXICITY:	Finished product is not expected to have chronic health effects. There is no specific data for this product.
SUSPECTED CARCINOGEN:	Finished product is not expected to be carcinogenic. There is no specific data for this product.

Section 12: Ecological information

ENVIRONMENTAL STABILITY:	There is no specific data for this product.
EFFECTS ON PLANTS AND ANIMALS:	There is no specific data for this product.
EFFECTS ON AQUATIC LIFE:	There is no specific data for this product.

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Section 13: Disposal consideration

WASTE DISPOSAL: Dispose of in accordance to federal, state, and local regulations.

SPECIAL CONSIDERATIONS: Dispose of in accordance to federal, state, and local regulations.

Section 14: Transport information

49 CFR (GRND): Not regulated.

IATA (AIR): Not regulated.

IMDG (OCN): Not regulated.

TGDR (CANADIAN GRND): Not regulated.

ADR/RID (EU): Not regulated.

SCT (MEXICO): Not regulated.

ADGR (AUSTRALIA): Not regulated.

Section 15: Regulatory information

SARA 313/302/304/311/312 CHEMICALS: None

OSHA: This product contains no chemicals which are hazardous by definition of the Hazard Communication Standard (29 CFR 1910.1200).

TSCA: All chemical substances in this product are listed on the TSCA inventory or are otherwise exempt from inventory status.

CERCLA REPORTABLE QUANTITY (RQ): None

OTHER FEDERAL REQUIREMENTS: This product complies with the appropriate sections of the Food and Drug Administration, Code of Federal Regulations (CFR) Title 21.

Section 16: Other information

The information contained herein is based on the state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. It does not represent a guarantee of the properties of the product.

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Supersedes edition: 00